Remarks/Arguments:

With the present response, claims 1, 3-33, 47, 48, 50, and 51 are pending, with claims 9, 12-16, 18-29, 48, and 50 having been previously withdrawn as a result of a Restriction Requirement.

The office Action, on page 2, paragraph 4, recites U.S. Patent No. 7,147,656 B2 to Andreas et al. ("Andreas") as an applied reference in combination with U.S. Patent No. 6,068,634 to Lorentzen Cornelius et al. ("Cornelius"). Page 3 of the Office Action and the form PTO-892 included with the Office Action, however, recite U.S. Patent No. 5,409,495 to Osborn ("Osborn"). A telephone call to the Examiner on August 8, 2008 clarified that Osborn was used in combination with Cornelius, and not Andreas.

Claim rejections

Claims 1, 3-6, 10, 11, 30-33, 47, and 51 stand rejected under 35 U.S.C. §103(a) as unpatentable over Cornelius in view of Osborn. Applicants respectfully traverse this rejection.

Of these rejected claims, claims 1 and 47 are independent. Claim 1 recites, *inter alia*, an introducer, having a retrograde portion and an anterograde portion, for deployment of an endoluminal device in a body lumen in a distal location from a proximal location. The device has a compressed configuration and an expanded configuration. The endoluminal device is mounted concentrically over the inner sheath in the compressed configuration. An anterograde sheath is attached proximally to the distal tip, mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer. The anterograde sheath has an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder. The introducer further includes *anchoring means* in at least one of the retrograde portion or the anterograde portion *for anchoring the endoluminal device proximal end after expansion of the proximal end into the expanded configuration* in the body lumen and for minimizing relative axial movement between the proximal end of the device and the body lumen *during unsheathing of a remaining portion of the endoluminal device distal of the proximal end*. Exemplary embodiments of the claimed anchoring means may include a balloon 120, illustrated in FIG. 2; a notch 150, illustrated in FIG. 4A; a tether 152, illustrated in FIG. 5A; or a balloon 120, illustrated in FIG. 7,

The Office Action alleges that Cornelius discloses an anchoring means (14) for anchoring the stent's proximal end *after the stent has been released and expanded*. Applicants respectfully traverse this interpretation of Cornelius. Cornelius discloses a stent delivery system

in which a stent 20 is released from sleeves 22 and 24 *upon expansion of balloon 14* by pulling out of the sleeves. Cornelius, Col. 4, lines 65-66. It is clear that balloon 14 of Cornelius does not anchor the stent's proximal end *after* the stent has been released and expanded, but in fact merely provides the mechanism for releasing the stent 20 from sleeves 22 and 24 and expanding the stent 20. Cornelius fails to disclose the claimed feature of anchoring means for anchoring the endoluminal device proximal end *after* expansion of the proximal end into the expanded configuration or means for minimizing relative axial movement between the proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end.

The Office Action further alleges that the balloon of Cornelius, if slightly expanded before the tip was moved distally to release the distal end of the stent could anchor the proximal end of the stent against axial movement. Office Action, p. 3, ll. 5-6. For several reasons, Applicants respectfully traverse this interpretation of Cornelius.

First, the Office Action fails to state where such feature is disclosed in Cornelius. The above Office Action allegation, therefore, merely amounts to an inherency argument. Applicant respectfully submits that Cornelius provides no disclosure of the ability to *distally* move the tip to release the distal end of the stent. In fact, distal sleeve 24 is attached along catheter 10 to distal end 27 of balloon 14 by means of an adhesive. The distal end also includes a tapered end 28 that may also be formed of the same adhesive. Cornelius, Col. 4, ll. 37-44 and FIG. 1. Applicants respectfully submit that the tip of Cornelius *cannot* be moved distally to release the distal end of the stent, as is improperly alleged in the Office Action.

Second, according to Cornelius, expansion of balloon 14 pulls balloon 14 out of sleeves 22, 24. Cornelius, Col. 4, ll. 65-66. The expansion of balloon 14 unsheaths stent 20 from sleeves 22, 24. Cornelius provides no disclosure of being able to anchor the proximal end of stent 20 *after expansion of the proximal end into the expanded configuration* in the body lumen *during unsheathing of a remaining portion of the endoluminal device distal of the proximal end*, as is recited in claim 1.

Osborn discloses an apparatus for implanting a stent that includes a central balloon 30 disposed such that, generally, the entire stent 25 is placed over central balloon 30. Osborn, Col. 7, lines 18-19. Central balloon 30 is the first of balloons 30, 33, 34 to be inflated and provides the primary radial expansion force necessary to expand the stent 25 to its larger implantation diameter. Id, Col. 7, lines 44-47. After central balloon 30 has been inflated, balloons 33, 34 are inflated. Id, Col. 7, lines 50-52. Because of their less compliant

construction, balloons 33 and 34 contain the central balloon 30 between them and, thus, limit the longitudinal expansion of the central balloon. Id, Col. 7, lines 63-65.

Similar to Cornelius, Osborn fails to disclose or suggest the claimed feature of anchoring means for anchoring the endoluminal device proximal end *after* expansion of the proximal end into the expanded configuration.

Because both Cornelius and Osborn fail to disclose the feature of anchoring means for anchoring the endoluminal device proximal end *after* expansion of the proximal end into the expanded configuration *during unsheathing of a remaining portion of the endoluminal device*, Applicants respectfully submit that the rejection of claim 1 fails to establish a *prima facie* case of obviousness. Applicants respectfully request reconsideration and allowance of claim 1.

Claim 47 recites, *inter alia*, an introducer for deployment of an endoluminal device in a body lumen in a distal location from a proximal location, the device having a compressed configuration and an expanded configuration. The introducer comprises a retrograde portion and an anterograde portion comprising a distal tip and an anterograde sheath attached proximally to the distal tip and mounted over at least a distal portion of the endoluminal device in the anterograde portion of the introducer. The anterograde sheath has an open proximal end such that distal movement of the anterograde sheath unsheathes the portion of the endoluminal device contained thereunder. The introducer further includes a shaft attached to the distal tip and extending concentrically through a central lumen defined by the anterograde portion and retrograde portion and an inner sheath mounted concentrically over the shaft. An endoluminal device is mounted concentrically over the inner sheath in the central lumen and having a distal portion contained by the anterograde portion and a proximal end contained by the retrograde portion. The distal portion is constrained in the compressed configuration by the anterograde sheath and is adapted to expand into an expanded state as the anterograde sheath is advanced distally. *An inflatable balloon is mounted radially inside only the retrograde portion and is sized to anchor the endoluminal device proximal end against the body lumen after expansion of the proximal end into the expanded configuration* to minimize relative axial movement between the proximal end of the device and the body lumen *during unsheathing of the endoluminal device distal portion*. An exemplary embodiment of the claimed invention is illustrated in FIG. 2.

As discussed above with respect to claim 1, both Cornelius and Osborn fail to disclose the feature of a balloon sized to anchor the endoluminal device proximal end *after* expansion of the proximal end into the expanded configuration *during unsheathing of the endoluminal device distal portion*. Because both Cornelius and Osborn fail to disclose the feature of anchoring means for anchoring the endoluminal device proximal end *after* expansion of the proximal end

into the expanded configuration, Applicants respectfully submit that the rejection of claim 47 fails to establish a *prima facie* case of obviousness. Applicants respectfully request reconsideration and allowance of claim 47.

Claims 7, 8, and 17 stand rejected under 35 U.S.C. §103(a) as unpatentable over Cornelius in view of Osborn and further in view of U.S. Patent No. 6,022,336 to Zadno-Azizi et al. ("Zadno-Azizi"). Claims 7, 8, and 17 ultimately depend from claim 1.

Zadno-Azizi is cited for allegedly disclosing the use of a reinforcing layer to provide increased stiffness and for providing variable stiffness along the length of an introducer. Zadno-Azizi fails to make up for the deficiencies discussed above with respect to claim 1. Applicants therefore respectfully submit that claims 7, 8, and 17 are allowable over the proposed combination of Cornelius, Osborn, and Zadno-Azizi for at least the same reasons set forth above with respect to claim 1. Applicants respectfully request reconsideration and allowance of claims 7, 8, and 17.

Withdrawn claims

Claims 9, 12-16, 18-29, 48, and 50 are presently withdrawn. For withdrawn claims dependent upon claims deemed to be allowed in the next Office Action, Applicants respectfully request reintroduction and allowance of these claims.

Conclusion

In light of the above remarks, Applicants respectfully submit that the pending application is in condition for allowance. Applicants respectfully request reconsideration and allowance of the claims.

Respectfully submitted,

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